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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,982	10/21/2003	Paolo La Colla	06171.105003 (IDX 1003 US	8969
57263 7590 06/01/2007 KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER BALASUBRAMANIAN, VENKATARAMAN	
			ART UNIT 1624	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/689,982

Applicant(s)

COLLA ET AL.

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7,9 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-7, 9 and 11-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, which included cancellation of claims 2, 10, addition of new claims 13-21 and amendment to claims 1, 3, 5, 8, 11 and 12, filed on 3/6/2007, is made of record. Claims 1, 3, 5-7, 9 and 11-21 are now pending. In view of applicants' response, the 112 second and first paragraph rejections made in the previous office action have been obviated. In addition, the 102 rejections have been obviated. However, the following rejections are applied to the currently pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5-7, 9 and 11-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Insertion of "optionally" in claim 1 in the definition of R is deemed as new matter. The originally presented claims R to have heteroatoms and is not optional. Specification does not provide support for the term "optionally" for R choices. This is clearly new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-7, 9 and 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Artico et al., WO 96/10565.

Artico et al., teaches several 6-benzyl-4-oxypyrimidines for treatment of viral infections such as HIV, which include instant compounds, composition, process of making and method of use. See page I, formula I. With the given definition of various

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variable groups, compounds taught by Artico include instant compounds. See entire document, especially Table 2-5 for various compounds made.

While said compound doesn't anticipate the scope of instant claims due applicants' amendment to Z excluding H as a choice, they are very closely related, being homolog that is compounds that differ in H in the reference on vs. methyl in the instant benzyl group. However, homologs and compounds that differ only by CH₃ Vs H are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Wood* 199 USPQ 137; *In re Lohr* 137 USPQ 548.

Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Claims 1, 3, 5-7, 9 and 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aroyan et al., *Arm. Khim. Zh.* 24(2): 161-166, 1971 (cited in the IDS).

See compounds shown in the CAPLUS Abstract.

While said compound doesn't anticipate the scope of instant claims due applicants' amendment to Z excluding H as a choice, they are very closely related, being homolog that is compounds that differ in H in the reference on vs. methyl in the instant benzyl group. However, homologs and compounds that differ only by CH₃ Vs H are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Wood* 199 USPQ 137; *In re Lohr* 137 USPQ 548.

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Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-23 of U.S. Patent No. 6,545,007. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter namely compound and pharmaceutical composition embraced in the instant claims are also embraced in the pharmaceutical composition claims 20-23 of the US 6,545,007. Note claim 20 includes instant compounds and the composition. Thus, it would be obvious to one trained in the

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art to make the pharmaceutical composition including those compounds embraced in the instant claims and expect the said composition useful as pharmaceuticals.

While said compound doesn't anticipate the scope of instant claims due applicants' amendment to Z excluding H as a choice, they are very closely related, being homolog that is compounds that differ in H in the reference on vs. methyl in the instant benzyl group. However, homologs and compounds that differ only by CH₃ Vs H are not deemed patentably distinct absent evidence of superior or unexpected properties. See *In re Wood* 199 USPQ 137; *In re Lohr* 137 USPQ 548.

Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

Claims 1-3, 5-7, 9 and 11-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, 17-25 and 30-46 of copending Application No. 10/350,772. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter namely the pharmaceutical composition of compound of formula A and the method of use embraced in the instant claims are also embraced in the pharmaceutical composition of compound of formula A and method of use claims 1-15, 17-25 and 30-46 of copending application 10/350,772. Thus, it would be obvious to one trained in the art to make the pharmaceutical composition including those compounds embraced in the instant claims and expect the said composition useful as pharmaceuticals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is same as made in the previous office action. Applicants have differed addressing this rejection. As noted above, this rejection is proper and is maintained.

Claims 1-3, 5-7, 9 and 11-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 and 29 of copending Application No. 11/327,672. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter namely the pharmaceutical composition of compound of formula A and the method of use embraced in the instant claims are also embraced in the compound of formula A, pharmaceutical composition of compound of formula A and method of use claims 1-25 and 29 of copending application 11/327,672. Thus, it would be obvious to one trained in the art to make the pharmaceutical composition including those compounds embraced in the instant claims and expect the said composition useful as pharmaceuticals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection is same as made in the previous office action. Applicants have differed addressing this rejection. As noted above, this rejection is proper and is maintained.

Claims 1-3, 5-7 and 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 37-80 of

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copending Application No. 10/833,601. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter namely the pharmaceutical composition of compound of formula A and the method of use embraced in the instant claims are also embraced in the compound of formula I, pharmaceutical composition of compound of formula I and method of use claims 1-8 and 37-80 of copending application 10/833,601. Thus, it would be obvious to one trained in the art to make the pharmaceutical composition including those compounds embraced in the instant claims and expect the said composition useful as pharmaceuticals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection is same as made in the previous office action. Applicants argued that Z is not carbon in the copending application. This is incorrect. Z is permitted to be carbon as well. See entire claim set. Hence, this rejection is proper and is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

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5/29/2007